cocaine, atropine and morphine. While each of these substances can be used to affect human physiology, *nicotine has a particularly broad range of influence."*[10]

Similarly, RJR scientists have reported that smokers who inhale lightly appear to use tobacco to achieve "mental activation and performance enhancement" whereas those who inhale more deeply show brain effects that "may reflect the anxiolytic properties of benzodiazepines,"[11] prescription drugs used to alleviate anxiety. Another RJR researcher has stated:

> [I]n different situations and at different dose levels, *nicotine appears to act as a stimulant, depressant, tranquilizer, psychic energizer, appetite reducer, anti-fatigue agent, or energizer. . . .* Therefore, in addition to competing with products of the tobacco industry, *our products may, in a sense, compete with a variety of other products with certain types of drug action.*[12]

Thus, the industry's own documents acknowledge that the pharmacological effects of their products are the same as the effects the Agency has considered to be structure-function effects within the meaning of section 201(g)(1)(C). Notwithstanding the views of their own scientists, the tobacco industry comments publicly assert that cigarettes and smokeless tobacco do not affect the structure or any function of the body within the meaning of the Act because their effects are too "remote" or not therapeutic or beneficial.

The ramifications of the tobacco industry's position are far-reaching. If the Agency were to determine that the pharmacological effects of cigarettes and smokeless

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[10] Philip Morris Inc., Draft Report Regarding a Proposal for a "Safer" Cigarette, Code-named *Table* (emphasis added). *See* AR (Vol. 531 Ref. 122).

[11] Pritchard WS, R.J. Reynolds Tobacco Co., Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485, at 488. *See* AR (Vol. 3 Ref. 23-2).

[12] Teague CE, R.J. Reynolds Tobacco Co., *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 1-2 (emphasis added). *See* AR (Vol. 531 Ref. 125).

tobacco are not effects on the structure and function of the body, or are not significant effects, the Agency's authority to regulate other products with like pharmacological effects—sedation, stimulation, weight loss, and satisfaction of addiction—would be called into question. Under the industry's characterization of the effects of their products, even if the pharmacological effects of sedation, stimulation, weight loss, or satisfaction of addiction were expressly promoted or otherwise intended, products producing the same effects could not be regulated under section 201(g)(1)(C) or 201(h)(3) because, by the industry's definition, these products would not "affect the structure or any function of the body." This view, if accepted, could undermine the Agency's ability to regulate drugs and devices that are not used in the diagnosis or treatment of disease, but significantly affect the structure or any function of the body. Further, such an interpretation would be inconsistent with over 50 years of Agency practice since passage of the Act in 1938.

In sum, cigarettes and smokeless tobacco do affect the structure and function of the body within the meaning of the Act. The pharmacological effects of nicotine-containing tobacco products are significant and the same as the effects of other products traditionally regulated by FDA. Because these effects are "intended" within the meaning of the Act—the issue discussed in section II., below—cigarettes and smokeless tobacco fall within the jurisdiction of the Agency under the Act.

B. RESPONSE TO COMMENTS

1. As noted in section I.A., above, tobacco industry comments and others argue that the effects of nicotine delivered from cigarettes and smokeless tobacco are too remote or insignificant to be subject to the Act. These comments minimize nicotine's

effects and argue that nicotine-containing tobacco products "stimulate the senses" and "calm[] feelings of stress," more like the effects of "hammocks [and] gardening tools" than those of products within FDA's jurisdiction.[13] The industry comments urge the Agency to follow the holding of *FTC v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573 (S.D.N.Y. 1952), *aff'd*, 203 F.2d 955 (1953), where the court concluded that the "soothing" effects of cigarettes do not affect the structure and function of the body.

FDA disagrees with these comments. As described earlier in this section, nicotine's effects on the structure and function of the body are comparable both in quality and quantity to those of tranquilizers, stimulants, weight control products, and products for long-term maintenance of addiction. These effects have long been recognized as effects on the structure or function of the body that are within FDA's jurisdiction. In addition, the Act's legislative history and case law interpreting the Act provide ample support for the conclusion that nicotine's effects are significant and within the scope of the Act. While "remote physical effect[s] on the body" may not be sufficient to invoke the Act's jurisdiction, *see Squibb,* 870 F.2d at 682, nicotine produces significant pharmacological and physiological effects on the structure and function of the body, and these effects clearly fall within sections 201(g)(1)(C) and 201(h)(3).

The courts have held that effects much less significant than those of nicotine are effects on the structure or function of the body and are within FDA's jurisdiction.

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[13] Joint Comments of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 241. *See* AR (Vol. 526 Ref. 95).

Joint Comments of the Cigarette Manufacturers, Comment (Jan. 2, 1996), vol. II, at 65-66. *See* AR (Vol. 535 Ref. 96).

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Products whose effects have been found sufficient to fall within the scope of sections 201(g)(1)(c) and 201(h)(3) include those for temporary smoothing of wrinkles, *United States v. . . . "Line Away, Temporary Wrinkle Smoother,"* 284 F. Supp. 107 (D. Del. 1968), *aff'd*, 415 F.2d 369 (3d Cir. 1969); *United States v. . . . "Sudden Change,"* 409 F.2d 734 (2d Cir. 1969); and products that deliver low levels of oxygen for recreational use to enhance athletic performance, *United States v. . . . "Sports Oxygen,"* Civ. No. 89-2085 (D.N.J. Oct. 27, 1992*), reprinted in Federal Food, Drug, and Cosmetic Act: A Judicial Record, 1991-92,* 110-119. These effects are plainly less significant than the potent psychoactive, addictive, and weight-regulating effects of nicotine.

Weight loss is one of the effects of cigarettes and smokeless tobacco. *See* section II.A.4., below. Courts have held that this type of effect alone is sufficient to make cigarettes a drug when the product is "intended to affect the structure and functions of the human body by . . . achieving a reduction in the body's weight." *United States v. 354 Bulk Cartons . . . "Trim Reducing-Aid Cigarettes,"* 178 F. Supp. 847, 851 (D.N.J. 1959). Similarly, the legislative history of section 201(g)(1)(C) also demonstrates that weight loss alone is an effect on the structure and function of the body within the meaning of the Act. Indeed, one of the principal reasons cited by Congress for broadening the definition of "drug" to include products that affect the structure or function of the body was to bring weight control products within FDA's jurisdiction. *See* 78 Cong. Rec. 8960, 73d Cong., 2d Sess. (May 16, 1934) (statement of Senator Copeland), *reprinted in A Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments* (hereinafter Legislative History), vol. 2, at 831.

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The Agency disagrees that the effects of nicotine in cigarettes and smokeless tobacco are comparable to those produced by hammocks, gardening tools, or other similar articles. First, such articles do not introduce chemical ingredients into the body. By contrast, cigarettes and smokeless tobacco deliver a potent chemical ingredient, nicotine, whose significant pharmacological effects on the human body are widely recognized in the scientific community. Second, the powerful psychoactive effects produced by nicotine in cigarettes and smokeless tobacco are comparable to those produced by tranquilizers, stimulants, weight management agents, and drugs used for long-term maintenance of addiction, all of which are indisputably within FDA's jurisdiction. Third, as described in section I.A., above, tobacco industry officials have acknowledged that nicotine's effects are comparable to those of prescription drug products.

FDA also disagrees that the 1952 decision, *Liggett & Myers*, 108 F. Supp. 573, represents a controlling determination that cigarettes do not affect the structure or function of the body within the Act's meaning. Much less was known about the addictive, psychoactive, and weight-regulating effects of nicotine when the court decided *Liggett* in 1952 than is known today. The kinds of effects that were alleged in *Liggett* (lack of irritation to the respiratory system and "soothing" effects) are far different from the addicting and other psychoactive and weight-regulating effects now known to be caused by nicotine in cigarettes. *See* sections II.A.1. and IV., below. Moreover, *Liggett* was decided before FDA regulated nicotine. The Agency now regulates nicotine-containing products such as nicotine transdermal patches and nicotine nasal spray intended to treat nicotine addiction. If nicotine were not a powerful pharmacological agent with addictive

properties, nicotine cessation products would be unnecessary. Further, the *Liggett* opinion does not suggest that the definition of "drug" would preclude treating cigarettes as drugs if new evidence concerning cigarettes' effects became known. *See* section IV., below.

Accordingly, FDA concludes that nicotine's significant pharmacological effects are effects on the structure or function of the body within the Act's meaning.

2. Tobacco industry comments contend that Congress intended to limit the drugs and devices covered by sections 201(g)(1)(C) and 201(h)(3) (products "intended to affect the structure or any function of the body") to products with "therapeutic" or "medical" uses. One industry comment further elaborates that the structure-function provision was added to the Federal Food, Drug, and Cosmetic Act in 1938 only as a result of concern that certain "therapeutic" products used for weight management purposes had escaped regulation under the 1906 Pure Food and Drug Act because obesity and leanness were not considered to be diseases. Consequently, this comment argues, the structure-function provision encompasses only products intended for "therapeutic" or "medical" use in "disease-treatment" conditions.[14]

This industry comment also makes a related argument that effects on the structure or function of the body must be "beneficial," or "drug-like," and not "destructive or toxic." According to this comment, "FDA views 'addictiveness' as an undesirable characteristic, not as a beneficial effect, and therefore more as a form of toxicity."[15] This

[14] Joint Comments of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 145-146. *See* AR (Vol. 526 Ref. 95).

[15] *Id.* at 151.

comment argues that the effects of cigarettes and smokeless tobacco are therefore outside the scope of the Act.

Conversely, one public interest group comment argues that construing sections 201(g)(1)(C) and 201(h)(3) as requiring a "therapeutic" effect would make these sections redundant of sections 201(g)(1)(B) and 201(h)(2), which define drugs and devices as products "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." According to this comment, such an interpretation would violate basic rules of statutory construction.

The Agency disagrees with the tobacco industry's narrow reading of the structure-function provision. Neither the language of the statute, its legislative history, nor the case law supports the position that drugs and devices must have "therapeutic," "medical," or "beneficial" effects or purposes in order to "affect the structure or any function of the body."

The plain language of the statute provides no support for the tobacco industry's position. The terms, "therapeutic," "medical," and "beneficial," or words of similar import, do not appear anywhere in section 201(g)(1)(C) or 201(h)(3). FDA agrees with the comments that assert that construing the "structure or any function" language to require a therapeutic or medical effect would make these provisions essentially identical in scope and meaning to sections 201(g)(1)(B) and 201(h)(2). To do so would violate the well-accepted principle that "a legislature is presumed to have used no superfluous words." *Bailey v. United States*, 116 S.Ct. 501, 507 (1995).

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The legislative history is also inconsistent with the tobacco industry's position. Congress added sections 201(g)(1)(C) and 201(h)(3) to broaden the coverage of the Act to include a "comprehensive class of preparations which were intended to affect the structure or function of the body." *"Line Away,"* 284 F. Supp. at 110 (citations omitted). The Act's legislative history makes clear that Congress intended to *expand* the Act's jurisdiction, rather than merely "close a loop-hole" in subsection 201(g)(1)(B). *See, e.g.*, H.R. Rep. No. 2139, 75th Cong., 3d Sess. 2 (1938), *reprinted in* 6 Legislative History 301 ("Drugs intended . . . for remedying underweight or overweight or for *otherwise* affecting bodily structure or function are subject to regulation") (emphasis added); *see also American Health Products Co. v. Hayes,* 574 F. Supp. 1498, 1506 (S.D.N.Y. 1983) (The structure-function provision was enacted to "reach those products . . . which evaded regulation altogether because they were neither foods *nor therapeutic agents*") (emphasis added).

The inclusive nature of the structure-function provision was raised several times during the hearings that led to enactment of the 1938 Act. *See Hearings on S. 1944, Senate Subcomm. of the Comm. on Commerce,* 73d Cong., 2d Sess. 15 (1933), *reprinted in* 1 Legislative History 107 ("The definition of the term 'drug' has been widened"); *Hearings on S. 2800, Senate Comm. on Commerce*, 73d Cong., 2d Sess. 516 (1934), *reprinted in* 2 Legislative History 519 ("This definition of 'drugs' is all-inclusive"); *Hearings on S. 5, Senate Comm. on Commerce*, 74th Cong., 1st Sess. 352 (1935), *reprinted in* 3 Legislative History 546 ("There is a universal recognition that the definition of the term 'drug' in the third subdivision is inclusive"). Congress consistently rejected

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suggestions to limit the drug definition to products with medical or medicinal purposes. *See, e.g., Hearings on S. 2800, Senate Comm. on Commerce*, 73d Cong., 2d Sess. 515-516 (1934), *reprinted in* 2 Legislative History 518-519.

Judicial decisions and Agency practice also conflict with the narrow interpretation urged by the manufacturers. As the Supreme Court has stated:

> Viewing the structure, the legislative history, and the remedial nature of the Act, . . . it [is] plain that Congress intended to define "drug" far more broadly than does the medical profession. . . .
>
> . . . the word "drug" is a term of art for the purposes of the Act, encompassing far more than the strict medical definition of that word. If Congress had intended to limit the statutory definition to the medical one, it could have so stated explicitly.

United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 793 (1969).

The structure-function provision has been applied since 1938 to a wide assortment of products with a range of uses and effects, many of which cannot be considered "therapeutic." For example, products that have been found to be within this provision include those with cosmetic, recreational, economic, or other nontherapeutic purposes. These products include tanning booths; sunscreens; breast implants; injectable collagen; birth control pills; products purporting to remove wrinkles temporarily, *e.g., "Line Away," "Sudden Change";* products intended to eliminate pet odors, *e.g., United States v. Undetermined Quantities . . . "Pets Smellfree,"* 22 F.3d 235, 240 (10th Cir. 1994); products intended to grow hair, *e.g., United States v. Kasz Enterprises, Inc.*, 855 F. Supp. 534, 540 (D.R.I.), *modified on other grounds,* 862 F. Supp. 717 (D.R.I. 1994); products intended as aphrodisiacs, *see* 54 FR 28780 (July 7, 1989), 21 CFR 310.528; products intended to enhance athletic performance by delivering a low, non-therapeutic level of

oxygen, *e.g.*, *"Sports Oxygen"*; and veterinary products intended to increase milk production, *e.g.*, *United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219 (D. Minn. 1991), *aff'd*, 968 F.2d 681 (8th Cir. 1992).

In the case of tanning booths, the Agency considers the product to be a "device" intended to affect the structure or any function of the body despite the fact that the American Academy of Dermatology considers tanning booths to be a potential health hazard and discourages their use.[16] FDA even regulates veterinary products intended to induce death in animals by humane means—an intended use that is indisputably not therapeutic. *See United States v. Articles of Drug . . . "Beuthanasia-D Regular,"* Civ. No. 77-0-396 (D. Neb. August 1, 1979), *reprinted in Federal Food, Drug, and Cosmetic Act: A Judicial Record, 1978-80,* 83-89.

The nature of a product's effect on the structure or function of the body—therapeutic or non-therapeutic, beneficial or adverse—thus does not determine FDA's jurisdiction. The relevant inquiry is simply whether a product has an effect on the structure or any function of the body. Cigarettes and smokeless tobacco do have such effects and, moreover, the effects are achieved through pharmacological means. The tobacco industry comments admit that products with "drug-type characteristics" (i.e., pharmacological action) are within the Act's jurisdiction.

[16] Photobiology Task Force of the American Academy of Dermatology, Risks and benefits from high-intensity ultraviolet A sources used for cosmetic purposes: special report, *Journal of the American Academy of Dermatology* 1985;12:380-381. *See* AR (Vol. 711 Ref. 17).